Citation:

Brehm BJ, Lattin BL, Summer SS, Boback JA, Gilchrist GM, Jandacek RJ, D'Alessio DA. One-year comparison of a high-monounsaturated fat diet with a high-carbohydrate diet in type 2 diabetes. *Diabetes Care.* 2009 Feb; 32 (2): 215-220.

PubMed ID: 18957534

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compared the effect of high-monounsaturated fatty acid (MUFA) and high-carbohydrate (CHO) diets on body weight and glycemic control in men and women with type 2 diabetes.

Inclusion Criteria:

- BMI of 27-40kg/m^2
- Age 30-75 years
- Stable body weight for the preceding six months
- Diagnosis of type 2 diabetes for at least six months, A1C of 6.5-9.0%, and treatment with diet or oral agent only (no insulin).

Exclusion Criteria:

- Pregnancy or lactation
- Active cardiac, pulmonary, renal, liver or gastrointestinal disease
- Untreated thyroid disease or hypertension
- Triglyceride concentrations ≥500mg/dL
- Use of medication that may alter lipid metabolism (other than HMG-CoA reductase inhibitors), corticosteroids and weight loss drugs.

Description of Study Protocol:

Recruitment

Subjects were recruited by advertisement.

Design

- The study used a randomized controlled trial design; subjects were randomly assigned for one year to either a high-MUFA or high-CHO diet
- A sub-sample of subjects were followed for an additional 18 months following the completion of the one-year intervention.

Dietary Intake/Dietary Assessment Methodology

To monitor food intake, subjects kept three-day food records during each week they were scheduled to have a session with the study dietitians.

Blinding Used

Not applicable.

Intervention

Subjects were randomly assigned to one of the following diets for 52-weeks:

- High-MUFA: 45% CHO, 15% protein, 40% fat (20% MUFA)
- High-CHO: 60% CHO, 15% protein, 25% fat.

Diet plans were individualized to include 200-300 calories per day less than calculated energy needs to allow for 1/2 pounds per week weight loss. Subjects were also asked to maintain their level of physical activity and not initiate more vigorous regiments during the 52-week study.

Statistical Analysis

- Intention-to-treat analyses were performed using estimated values for missing data
- Baseline characteristics were compared between the two groups using T-tests
- To assess the effects of the diets, the anthropometric measures, blood pressure, lipid measurements, A1C, and plasma glucose and insulin were the dependent variables, while diet was the independent variable
- For the main analyses, mixed models were used for each dependent variable, with the covariates of age, race, sex and adherence rating
- Analyses were run for all data collected, only data from subject who completed the study and for all participants but with estimates for missing data inserted
- Multiple regression was used for imputation of missing data with predicted values based on age, sex, race and adherence
- Level of significance was set at $P<0.05$
- The results presented are based on the participants who completed the intervention (N=95). Intention-to-treat analyses using estimated data for missing values of all participants yielded similar results.

Data Collection Summary:

Timing of Measurements

- Baseline: Height, weight, waist circumference, blood pressure, blood samples, body composition. Reassessment of these measures was made after four, eight and 12 months of dieting
- Participants met with a dietitian weekly during months one and two, bi-weekly during months three and four, and monthly during months five through 12 for either individual counseling or a group session (alternating every other visit). Three-day food records and physical activity records were provided at each of these sessions, and weight was measured
- Extension study: A sub-sample of subjects were invited to participate in an extension study, where 18 months after completion of the intervention, measures of weight, height, waist circumference, body composition, blood pressure, A1C, and lifestyle habits were assessed. There was no contact between the subjects and research team during the 18 months.

Dependent Variables

- Weight measured in duplicate by study personnel
- Waist circumference
- Blood pressure
- Blood samples were taken to assess total cholesterol, HDL cholesterol, triglycerides, A1C, glucose and insulin
- Body composition was measured using dual-energy X-ray absorptiometry (DXA).

Independent Variables

- Diet type:
  - High-MUFA
  - High-CHO.

Control Variables

- Age
- Sex
- Race
- Study adherence (measured by subjects and dietitians using a 10-point rating scale).

Description of Actual Data Sample:

- *Initial N:* N=124 overweight or obese individuals (46 men and 78 women)
- *Attrition (final N):* N=95
  - 52 in high-CHO (17 men, 35 women)
  - 43 in high-MUFA (17 men, 26 women)
  - Subjects dropped out due to relocation, work schedules, family responsibilities; only three left for diet-related reasons
  - No differences in sex, race or age between participants who completed the study and those who dropped out of the study
- *Age:* 37.9-74.9 years
- *Ethnicity:* Initial sample included 92 Caucasians and 32 African Americans
- *Other relevant demographics:* None reported
- *Anthropometrics:*
  - BMI=35.9±0.3kg/m^2
  - Waist circumference=111.9±1.1cm
  - Body fat=38.0±0.6%
  - A1C=7.3±0.1%
- *Location:* United States.

Summary of Results:

- Subjects consumed approximately 1,550kcal per day. The high-MUFA group consumed 46% of total energy as CHO and 38% as fat. The high-CHO group consumed 54% of total energy as CHO and 28% as fat. Both diet groups consumed comparable amounts of protein, saturated fat and cholesterol
- Both groups had significant reduction in weight over 52 weeks, but there was no difference in weight loss between the groups
- Reduction in BMI was similar in both groups after 12 months
- Changes in body composition were similar in both diet groups over time, with decreased body fat and lean body mass (P<0.0001) and waist circumference (P<0.01), but no differences between the groups
- In the extension study, there were no significant changes in the participants weight, BMI, waist circumference, body fat, blood pressure or A1C from the completion of the 52-week diet to the final assessment 18 months later.

	High-CHO				High-MUFA			
	Baseline	4 months	8 months	12 months	Baseline	4 months	8 months	12 months
Body weight (kg)	102.1±2.0*	98.2±2.0	98.3±2.1	98.3±2.0	103.7±2.8*	99.2±2.8	99.3±2.9	99.7±3.0
Lean body mass (kg)	62.1±1.5*	61.6±1.6	61.9±1.6	61.3±2.2	63.2±2.2*	62.5±2.2	63.0±2.2	62.5±2.2
Body fat (kg)	38.9±1.0*	36.5±1.1	36.3±1.1	37.1±1.1	38.8±1.3*	35.6±1.6	36.3±1.4	36.9±1.4
Blood pressure (mmHg)	130/77±2/1.6*	128/73±2.2/14	130/74±2.3/1.1	129/73±2.3/1.4	132/78±2.3/1.4*	128/73±2.7/1.2	127/75±2.3/1.3	130/73±2.4/1.5
Total Cholesterol (mg/dL)	178±4.9	183±5.1	188±5.5	180±5.2	179±7.2	177±6.3	182±6.4	184±6.5
Triglycerides (mg/dL)	182±17.9	179±14.9	174±12.7	177±17.4	202±17.3	188±14.6	197±27.2	201±20
LDL (mg/dL)	100±4.6	103±4.9	107±5.1	97±4.9	104±7.0	99±6.5	104±5.9	101±6.1

HDL (mg/dL)	43±1.4*	44±1.4	46±1.4	48±1.4	42±1.2*	44±1.2	46±1.3	47±1.3
A1C (%)	7.2±0.1*	6.8±0.1	7.1±0.2	7.2±0.2	7.4±0.1*	6.8±0.2	7.0±0.2	7.5±0.3
Glucose (mg/dL)	135±4.7*	122±4.4	137±7.3	127±5.5	150±7.0*	130±6.4	141±7.7	142±8.1
Insulin (pmol/L)	314±37.1*	283±23.4	260±23.9	287±26.7	309±25.4*	244±17.2	217±14.7	251±23.6
HOMA-IR	7.6±0.6*	7.0±0.6	7.4±0.9	7.6±0.8	9.2±0.8*	6.7±0.6	6.7±0.8	7.8±1.0
***P<0.01 (significant time effects)**								

Author Conclusion:

Individuals with type 2 diabetes stand to benefit in terms of weight, body composition, cardiovascular risk factors and glycemic control from following diets high inMUFA or high in CHO.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes

4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes

	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes